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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,280	12/21/2000	Michinobu Nakamura	197748US0PCT	5123

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,280	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *7,8,14,15 and 22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *7,8,14,15 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/2004 has been entered.

Status of claims

Claims 7, 8, 14, 15 and 22-26 as amended [1/14/2004] are pending and under examination.

Claims 1-6 were canceled by applicants [Paper(s) filed 10/29/20011].

Claims 9-13 and 16-21 were canceled by applicants [Paper(s) filed 5/14/2002].

Claim Rejections - 35 USC § 112

Claims 7, 8, 14, 15 and 22-26 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the sample" that is/are in a liquid state (see last line of claim 7). There is insufficient antecedent basis for this limitation in the claim because there is no recitation about "sample(s)" in none of the steps (1) to (3). It is uncertain and unclear what is "sample" in each (1) to (3), what is protocol to obtain the "sample(s)", how much and when water is added to produce/to obtain sample(s) in liquid state as intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/28853.

The claims are directed to a method for producing hydrolyzed protein from vegetable protein material wherein the method comprises step of preparing a fungal koji mold culture inoculum, step of mixing the fungal koji mold culture inoculum with a vegetable protein material and step of conducting enzymatic hydrolysis at first temperature of about 15-39°C or about 25-38°C with aeration and agitation and then at second temperature of about 41-50°C wherein the method is practiced in a liquid state system in a submerged culture fermenter. The final hydrolyzed protein contains 5% and less reducing sugars. The temperature shift is conducted at the time of 10-60% completion of enzymatic hydrolysis. Some claims are further drawn to the use of vegetable protein materials such as wheat gluten or de-fatted soybean.

WO 95/28853 {Muller et al.} discloses a method for producing hydrolyzed protein or a seasoning sauce (see page 9, last paragraph) wherein the method comprises step of preparing a fungal koji mold culture *Aspergillus oryzae*, step of mixing the fungal koji mold culture with a vegetable protein material such as pretreated wheat gluten, step of conducting the 2-stage enzymatic hydrolysis at first temperature of about 30°C with aeration and agitation and then at second temperature of about 40-45°C.

Thus, the method of the cited patent WO 95/28853 teaches the use of two temperature stages during enzymatic hydrolysis that are within the claimed temperature ranges. The method of the cited reference is considered to encompass the use of a container or a fermenter for a liquid or a semi-liquid submerged fermentation because it teaches the use of protein material for hydrolysis that is a gluten suspension of "a marked liquefaction" (page 9, par. 2, line 3).

The cited reference also suggests the use of various vegetable materials including defatted soybeans (page 1, par. 1) in a method for producing hydrolyzed protein from vegetable materials.

Although the cited patent WO 95/28853 does not clearly indicate the concentration of reducing sugars in the final hydrolyzed protein product, their amounts are considered to be substantially similar, if not identical, to the presently claimed amounts because the identical vegetable materials are subjected to identical two-temperature stage enzymatic hydrolysis by using identical koji mold fungal culture as presently claimed and as disclosed by the cited patent. Thus, the final products would be substantially similar, if not identical, as result of practicing substantially similar protocols of making that comprise the use of the same materials as claimed and as disclosed. Moreover, the cited patent WO 95/28853 teaches making and obtaining a hydrolyzed protein product with a "lighter" color (see abstract) that is reasonably expected to develop due to the lack of reducing sugars which commonly have browning effects on the product coloration (see instant specification page 5, par. 3).

Although the cited patent WO 95/28853 does not clearly indicate the degree of completion of enzymatic reaction at the moment of temperature switch, the same vegetable material is hydrolyzed at the same conditions as claimed, and, thus, the degree of completion is

reasonably expected to be the same as in the claimed method, particularly in view that identical temperature ranges are used for producing hydrolyzed protein in the cited method and in the claimed method.

The cited patent WO 95/28853 does not clearly discloses the design of the container in the method for producing hydrolyzed protein. However, the cited patent US 4,808,419 (D) is relied upon to demonstrate that fermenters for submerged and for semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparations derived from *Aspergillus oryzae* are known in the art and they are commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of WO 95/28853 in a submerged culture fermenter-type reaction vessel with a reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419, for example, and because they are available for fermentation and hydrolysis of vegetable materials including koji fermentations. One of skill in the art is free to choose a fermenter suitable for koji fermentation that is known and/or available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited reference. Therefore, the claims are properly rejected under 35 U.S.C. 103.

Claims 7, 8 and 22-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 (A) in view of US 4,808,419 (D).

Claims as explained above.

US 6,045,819 (A) discloses a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of preparing a koji mold fungal culture inoculum including *Aspergillus oryzae* (col. 10, lines 30-39 and col. 11, lines 47-50), mixing the koji inoculum with a vegetable material such as de-fatted soybeans, step of conducting first stage fermentation at temperature about about 30°C with and then at second temperature of about 50°C (col. 11, lines 53-57). Thus, the cited patent teaches the use of two temperature stages during enzymatic koji fermentation and hydrolysis that are within the claimed temperature ranges. The cited patent is considered to encompass the use of a liquid state culture and, thus, the use of a submerged culture fermenter-type reaction vessel by disclosing addition of water and thus, a device capable to hold fermentation reaction with addition of water into reaction system (col. 11, lines 53 or 66) in the method for producing hydrolyzed protein. The final hydrolyzed product obtained by two stage temperature fermentation of the cited patent is substantially free from reducing sugars because the cited patent teaches that the glycosidic saccharide that are originally present in vegetable materials are decomposed to undetectable extend (col. 12, line 21 or line 31).

In addition, the cited patent US 6,045,8 19 (A) also teaches pre-treatment of vegetable material before enzymatic hydrolysis. The method of the cited patent encompasses step of pulverization of vegetable material prior to fermentation by teaching the use of soy powder or small granules (see col. 9, lines 11-20, for example). The cited method teaches a step of

pasteurization or sterilization of vegetable material prior to fermentation by teaching cooking and/or heating soybeans (Fig. 1). The cited method encompasses steps of removing air bubbles from vegetable material prior sterilization or cooking by teaching kneading vegetable material into blocks (col. 9, lines 22-23) or by teaching a cooking step which is reasonably expected to remove at least some air bubbles due to increase of temperature and evaporation. The cited method encompasses sequential steps of dispersing pulverized vegetable material in hot water, removing air bubbles and sterilizing by teaching cooking of vegetable material prior to enzymatic fermentation with koji mold fungal culture.

Thus, the method of the cited patent US 6,045,8 19 (A) is substantially similar to the claimed method because it comprises identical steps drawn to the use of two temperature stage enzymatic fermentation or hydrolysis of identical vegetable protein materials with substantially identical fungal culture such as koji mold fungus *Aspergillus oryzae* wherein the method results in the possession of identical hydrolyzed protein product that is substantially free from reducing sugars.

The cited patent US 6,045,8 19 is silent with regard to a particular design for a fermenter reaction vessel. But the cited patent US 4,808,419 is relied upon to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparations derived from *Aspergillus oryzae* are known in the prior art and that are commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of US 6,045,8 19 in a submerged culture fermenter-type reaction vessel in a liquid state as intended the presently claimed invention with a

reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419, for example, and they are available for fermentation and hydrolysis of vegetable materials including koji fermentations. One of skill in the art is free to choose a fermenter suitable for koji fermentation that is known and available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited patent. Therefore, the claims are properly rejected under 35 U.S.C. 103.

Claims 7, 8, 14, 15 and 22-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819and WO 95/28853 in view of US 5,888,561 and US 4,808,419.

The claims 7, 8 and 22-26 as explained above. Claims 14 and 15 are further drawn to pre-treatment of vegetable protein materials by steps of pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material prior to fungal fermentation.

The cited patents US 6,045,8 19 and WO 95/28853 are relied upon as explained above. They both teach methods for producing hydrolyzed vegetable protein material having substantially decreased amounts of reducing sugars by applying two temperature stage fermentation with koji mold fungal cultures.

WO 95/28853 is missing particular disclosure related to pre-treatment of vegetable materials prior to fermentation such as pulverizing, dispersing, removing air bubbles and

sterilizing the vegetable protein materials. However, the cited US 6,045,819 teaches pre-treatments steps as explained above.

Further, the cited US 5,888,561 is relied upon to demonstrate that pre-treatment of vegetable materials by pulverization and sterilization prior to koji mold fermentation is a conventional procedure (example 1) in the method for producing hydrolyzed proteins characterized by decreased amounts of reducing sugars (col. 1, line 63-66). In addition, the cited patent US 5,888,561 also discloses a step removing air bubbles from the pulverized and dispersed vegetable material prior to sterilization by teaching that soaked vegetable materials were subjected to vacuum before pasteurization (col. 3, line 48).

The cited patent US 4,808,419 is relied upon as explained above to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to subject the vegetable material to a pre-treatment prior to enzymatic fermentation in the methods of US 6,045,819 or WO 95/28853 as suggested by US 6,045,8 19 with a reasonable expectation of success in producing hydrolyzed proteins because pre-treatment including pulverization, dispersion, removing of air bubbles and sterilization are conventional procedures in the methods for koji mold fermentations as evidenced by US 5,888,561. Further, with respect to pulverization step, it is considered to be a choice of experimental design to pulverize the vegetable material to various sizes including that of 300 μm or less as encompassed by the claimed method in the absence of evidence to the contrary.

Moreover, the instant application does not regard the importance of size being 300 μm or less and it teaches alternative use of particle sizes more than 300 μm (see specification page 11, par. 3). One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market (US 4,808,419). Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. 103.

Response to Arguments

Applicants' arguments filed 1/14/2004 have been fully considered but they are not persuasive.

Applicants argue that the cited references do not teaches the use of a liquid state system (response page 7). This is not found true because US 6,045,819 {Takebe} clearly teaches addition of water and, thus, the use of liquid state system for making hydrolyzed proteins that are free from reducing sugars. The cited WO95/28853 {Muller et al.} teaches the use of a system at a "marked liquefaction" state and, thus, the use of liquid state system for making hydrolyzed proteins that are free from reducing sugars.

Applicants' argument that each step in the method has to be conducted in a liquid state does not appear to be clearly encompassed by the claimed invention because it is uncertain what is "sample" in each and every step, how much and when water is added to the "sample" at each and every step.

Nevertheless, as applied to the cited documents, the fact that in the cited WO 95/28853 {Muller et al.} the fungal inoculum is in a form of "bread cube(s)" covered/infected by koji

molds of Aspergillus rather than in a form of liquid suspension of spores of koji molds of *Aspergillus* does not necessarily means that the fungal inoculum is not enzymatically active. The hydrolysis has been completed as disclosed by the cited WO patent and, thus, the starting fungal inoculum was active enough for the process of making hydrolyzed proteins.

The cited US 6,045,819 {Takebe} is considered to encompass the use of inoculum in a liquid state or in a liquid spore suspension because it indicates the particular spore counts per g of material to be hydrolyzed. The spore count is commonly established for (evaluated in) liquid suspensions by diluting microbial spores or microbial colony forming units in the inoculum-containing samples. Thus, the starting inoculum or the starting inoculum sample has been present in liquid state in the method of the cited US 6,045,819 {Takebe}.

Applicants arguer that the "liquid koji" obtained prior to hydrolysis has a high protease activity of 304 units /ml (response page 8. par. 3). Yet, the claimed invention is not so limited. Moreover, the enzymatically active preparation, that is argued, is further diluted by mixing with unidentified amounts of vegetable materials and, thus, the "high" protease activity as argued does not appear to create structural differences in the methods in the absence of amounts and proportions of all materials that are combined for hydrolysis. Thus, the use of a liquid inoculum or the use of semi-solid/solid inoculum would not appear to affect the enzymatic hydrolysis or its degree/intensity/result.

Applicants appear to argue a remarkably short protein hydrolysis of 8-24 hours (response page 8, par. 3). However, the time period for completion would obviously depend on amounts of materials involved and on characteristics of the materials. Yet, the claimed invention does not

point out either the amounts of materials/components or the specific characteristics of materials/components that would provide for remarkable results as argued.

Applicants' Declaration filed 4/21/2003 has been reevaluated but still found not persuasive as explained in the prior office action. The results of Declaration do not appear to establish differences between "liquid state" fermentation and solid/semi-solid state fermentation. The results of the Figure B in the Declaration copy cannot be read. Therefore, the results of the Declaration are confusing as to the significance of the differences in the method productivity as presently argued.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

March 2, 2004

V. Afremova

VERA AFREMOVA

PATENT EXAMINER